

higher pressure inflation (each time by 1 atmosphere) until perfect balloon dilatation is achieved (12 cycles). CAPSID was used in 148 vessels, (126 pts): 80% of procedures were pain-free with a low dissection rate (7% type B and 2% type C) and only 2% needed stent implantation. At 6-mo follow-up, only 26% of pts had mild angina or a positive stress test, 12% angiographic restenosis and only 9% needed repeat PTCA.

Pressure-volume curves obtained by CAPSID demonstrate mechanisms of PTCA: stretching (parallel lines shifting to the right) vs. breaking atheroma (abrupt break in curve). In 31 pts who had a second angiogram - a break in curve had a 74% sensitivity and 100% specificity for predicting no restenosis.

Thus, CAPSID allows safer PTCA with less pain and dissections, decreased need for stenting, and less restenosis. The pressure-volume curves reflect PTCA mechanisms, may predict restenosis and direct strategies to prevent it.

## 928-11 Interventional Device Sizing: On Line QCA vs. Visual Assessment

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To assess the adequacy of interventional device sizing, we imaged non compliant coronary balloons of 3.25, 3.5, 3.75 and 4.0 mm during inflation with diluted contrast to 3, 8, 12 and 16 ATM. The images of 17 precision drilled lesion phantoms filled with Omnipaque, and of balloons, were acquired on Philips Itegrity system and on cinefilm in 5 inch II mode, at 70 kV. High resolution analog video images were captured using Pentium PC workstation, QCA was performed on line using modified QCA Plus package and off cinefilm in usual fashion. All images were assessed by a panel of 3 cardiologists to estimate balloon sizes and phantom reference diameters (D ref). The accuracy was expressed as the mean signed difference between "true" and measured values, mean absolute difference (MAD) was used for more detailed assessment of the systematic error. Precision was defined as a standard deviation of the measurements.

	Accuracy	Precision	MAD
Balloon, Panel, mm	0.4	0.2	0.4
Balloon, On Line QCA, mm	0.18	0.12	0.2
Balloon, Cine QCA, mm	0.11	0.13	0.1
D ref., Panel, mm	0.21	0.56	0.35
D ref., On Line QCA, mm	-0.01	0.05	0.06
D ref., Cine QCA, mm	0.01	0.08	0.07

The accuracy of the on line and cine QCA for D ref and balloon sizing was significantly higher than panel estimates ( $p < 0.01$ ).

**Conclusion:** Visual device sizing alone results in systematic erroneous undersizing of interventional devices, which may adversely affect stent outcomes.

## 928-12 Oversized Balloons, Low Inflation Pressure and Prolonged Coronary Dilatation Strategy Results in Dramatic Improvements in Angioplasty Results & Restenosis Rate: Early & Late Results

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We propose to perform coronary angioplasty (PTCA) using a balloon size/vessel diameter ratio of up to 1.2:1, a low inflation pressure and prolonged coronary dilatation strategy and to evaluate restenosis rate at nine months (mos). 228 consecutive patients (pts); 170 males and 58 females aged 58  $\pm$  10 years underwent PTCA. Gradual inflation was applied until balloon became fully expanded followed by a prolonged symptoms-limited dilatation at 4 atm. The maximum inflation pressure used was 5.5  $\pm$  1.4 atm (range 2-12) and the total inflation time was 8.4  $\pm$  6.5 min (2.56 min/inflation). One hundred and fourteen pts had single-vessel disease and 114 pts had multivessel disease. Diameter stenosis (DS) by Quantitative Angiography was 86  $\pm$  11%. PTCA was attempted in 414 lesions (21 lesions were not crossed by the guide wire because of complete occlusion in 13 pts or severe stenosis) and was successful (DS < 30%) in 98% of the dilated lesions with a residual DS of 16  $\pm$  10%. There was no abrupt closure and two pts had dissection that required bail-out stenting and subsequent CABG. Nine pts had minor dissection that did not require stenting. Hospital stay was 2.8  $\pm$  1.8 days. To-date, 159 (70%) pts had repeat angiography and exercise ECG at 9 mos (range 5-29). Restenosis (> 50% diameter stenosis) was found in 31 (19%) pts. Of these 31 pts, 6 had complete occlusion and 11 pts had repeat PTCA. DS in the remainder of pts was 17  $\pm$  11%. 132 pts had pre PTCA Bruce treadmill stress test; post PTCA exercise time to 1 mm ST depression was 7.5  $\pm$  2.6 min, and maximum ST depression was 0.4  $\pm$  0.08 mm compared to pre PTCA of

4.6  $\pm$  2.4 min.  $p < 0.001$  and 1.4  $\pm$  0.9 mm,  $p < 0.001$ , respectively. **Conclusions:** Oversized balloons with low inflation pressure and prolonged dilatation strategy has low complication rate and result in low (19%) restenosis rate at 9 mos. This was associated with a sustained improvement in symptomatic status and exercise variables. Further studies to compare this strategy with conventional PTCA are required.

## 928-13 Effects of large doses of contrast medium in complex coronary interventions

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Complex coronary interventions frequently require large amounts of contrast medium (CM), which are potentially nephrotoxic. There are no data on the limitations of CM dosages in patients (pts). In order to evaluate the effect of CM (> 500 ml) on kidney and neurologic function in pts. without known renal diseases we analyzed a cohort  $n = 110$  consecutive pts. ( $n = 48$  PTCA,  $n = 41$  stent,  $n = 21$  laserwire recanalization; 64  $\pm$  11 years, female 12%, body weight 74  $\pm$  11 kg), who received non ionic CM (Iopamidol 755.2 mg/ml, Iopromid 769 mg/ml/median: 570 ml, max: 1000 ml). After the procedure pts. were hydrated with  $\geq 1000$  ml saline infusions. Blood samples from each pat. for serum creatinine and serum urea before, 48 ( $n = 110$ ) and 72 hours ( $n = 40$ ) after intervention were obtained. After the intervention no renal or neurologic complications occurred. There were no significant differences between the serum creatinine and serum urea before and 48/72 hours after intervention. None of the pts. had an increase of serum creatinine of more than 25%.

Serum Creatinine (mg/dl)	Serum Urea (mg/dl)	n
- Before intervention 1.2 $\pm$ 0.1	14.7 $\pm$ 4.1	110
- 48 h after intervention 1.3 $\pm$ 0.2	15.3 $\pm$ 3.9	110
- 72 h after intervention 1.1 $\pm$ 0.3	15.0 $\pm$ 3.7	40

**Conclusion:** The application of up to 1000 ml of nonionic CM in well hydrated pts. at the commencement of the procedure and without impaired kidney function did not result in any renal or neurologic dysfunction. Further prospective studies in larger cohorts are necessary to evaluate the potential limits in CM dosing.

## 928-14 Low Individual Operator Coronary Interventional (CI) Volume Is Not Associated With Worse Outcome

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To assess the relationship between individual operator CI volume and incidence of complications, the in-hospital outcome at a single, moderate volume urban academic center was prospectively collected over a 3 year period. 1389 consecutive procedures were performed or supervised by 9 operators. 25.2% procedures involved multivessel CI. The mean ejection fraction was 59  $\pm$  15%, and there were 1.7  $\pm$  0.7 vessels diseased. Clinical indications included stable angina 22.5%, unstable angina 31.9%, acute MI 2.9%, post MI 20.6%, shock 3.0%, and restenosis 19.1. There were 20.7% type A, 55.5% type B, and 23.8% type C lesions. Average yearly operator volume ranged from 26-83 (mean 51  $\pm$  26). Operators have performed 590  $\pm$  268 CIs, with 10.0  $\pm$  4.3 years CI experience, with a mean angioplasty volume rating of 180  $\pm$  37 (> 170 = adequate). The in-hospital major complication rate was 1.4% (95% CI 0.7-1.89) for all CIs, including 2 deaths, 13 CABG, 3 arrhythmias, and 2 Q wave MI. The rate of complications in this study was lower than the 1995 SCAI registry (1.9%,  $n = 19594$ ,  $p < 0.05$ ), 1995 ACC database (3.9%,  $n = 38963$ ,  $p = 0.001$ ), Hartzler 1988 (2.3%,  $n = 5413$ ,  $p = 0.02$ ), and 1985-1986 NHLBI Registry (7.2%,  $n = 1801$ ,  $p = 0.001$ ). Thus, despite individual volumes below those being considered for credentialing, the overall outcome obtained was excellent.

## 928-15 Changes in Functional Health for Women versus Men One Year Following PTCA or CABG

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Previous research has suggested that functional health (FH) following PTCA or CABG is similar in women and men, but this research was based on small numbers of women. **Methods:** We administered the MOS-SF36 FH instrument to 186 women and 291 men, prior to and one year following their PTCA or CABG. Baseline data included demographics, risk factors, comorbidities, anatomy and symptoms. Repeated measures ANOVA was used to compare scores by sex, controlling for age, priority, number of diseased vessels